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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,715	04/27/2000	William E. Rich	16866-002810US	4439

20350 7590 02/04/2003

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

AHMED, SHEEBA

ART UNIT	PAPER NUMBER
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1773

12

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS12

Office Action Summary

Application N .

09/560,715

Applicant(s)

RICH ET AL.

Examiner

Sheeba Ahmed

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-4, 6-11, 13-36 and 76-93 is/are pending in the application.
- 4a) Of the above claim(s) 19-21 and 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-4, 6-11, 13-18, 22, 32-36, and 76-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 5, 7. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of species (3) "electrostatic interactions" for claim 17 and species (4) "ammonium group" for claim 18, with traverse, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that each of the species recited in claims 17 and 18 emerge from a common inventive concept and searching all species together places no undue burden on the Examiner. However, as pointed out in the Office Action mailed on October 22, 2002 (Paper No, 10), an election of species can be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims wherein an extensive and burdensome search is required for a multiplicity of species. Hence, claims 1-4, 6-11, 13-36, and 76-93 are still subject to the restriction/election requirement and claims 19-21 and 23-31 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected species.

Claims 1-4, 6-11, 13-18, 22, 32-36, and 76-93 are now under consideration.

Claim Objections

2. Claims 10 and 80 are objected to as being identical. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is dependent on claim 1 and recites that the hydrogel is polymerized on “the silicon oxide coating by depositing a solution comprising monomers onto the glass coating”. There is no antecedent basis for “the glass coating” and it is unclear whether “the glass coating” refers to “the silicon oxide coating” or to a different glass coating. Appropriate correction is required.

Claim 86 is dependent on claim 1 and recites that “the binding functionality is a reactive group selected from an epoxide and a carbonyldiimidazole”. Claim 86 recites an improper Markush group and should properly recite that the binding functionality is “selected from the group consisting of an epoxide and a carbonyldiimidazole”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 6-11, 13-17, 76, 78-86, and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergstrom (US 5,436,161).

Bergstrom discloses a biosensor comprising a metal surface with a surface layer capable of selective bimolecular interaction using activated surfaces for coupling desired ligands (Column 1, lines 15-22). The metal surface is a free electron metal such as copper, silver or aluminum, and a mono layer of a organic molecule, XRY, is applied to the metal surface wherein X binds to the metal and Y serves for coupling with the functional ligands. However, Y may be present in a biocompatible porous matrix such as a hydrogel wherein the matrix is utilized for binding the ligands (Column 4, lines 20-46). Y may be any number of groups used for immobilization in liquid chromatography techniques such as hydroxyl, carboxyl, amino, aldehyde, hydrazide, carbonyl, epoxy or vinyl group (Column 5, lines 1-5). A mixture of different organic molecules XRY may also be used (Column 5, lines 10-15). The matrix, i.e., the hydrogel, has a thickness of 5 to 10,000 angstroms (equivalent to 1 micrometer) (Column 5, lines 30-41). The hydrogel may be polysaccharide such as dextrin or cellulose, a water swellable organic polymer such as polyacrylic acid or polyacrylamide. The hydrogel can be derivitized to contain hydroxyl, carboxyl, amino, aldehyde, hydrazide, carbonyl, epoxy or vinyl groups (Column 5, lines 61-68). The hydrogel may be generated in situ from a suitable solution of monomers and subsequent crosslinking (Column 6, lines 14-20). Bergstrom also teaches that it is known to coat the metal film with silica and optionally treat it with a silanizing agent (Column 2, lines 9-15). The Examiner takes the position that the

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biosensor disclosed by Bergstrom is "removably insertable into a spectrometer" and that the analytes that it is capable of binding are in fact "detectable by a mass spectrometer". All limitations of claims 1-4, 6-11, 13-17, 76, 78-86, and 93 are disclosed in the above reference.

5. Claims 32-36 and 87-92 are rejected under 35 U.S.C. 102(b) as being anticipated Rembaum et al. (US 4,438,239).

Rembaum discloses a coated substrate used in chemical and analytical research (Column 1, lines 18-22) wherein aldehyde substituted microspheres can be formed in situ and grafted onto diverse substrates such as polymeric films, rods, tubes to form a hybrid coated material (Column 3, lines 25-45). Individual microspheres having been prepared having sizes from 100 angstroms to 10 microns or larger (Column 4, lines 11-15). The microsphere coated product can be used as a substrate to bind molecules containing functional groups reactive with hydroxyl, carboxyl or amine substituents (Column 4, lines 20-26). The microspheres may be formed of monomers such as acrylamide, methacrylamide, or dimethylaminomethacrylate (Column 5, lines 50-60) and examples of beads used include styrene (See example 7). The Examiner takes the position that the coated hybrid material disclosed by Bergstrom is "removably insertable into a spectrometer" and that the analytes that it is capable of binding are in fact "detectable by a mass spectrometer". All limitations of claims 32-36 and 87-92 are disclosed in the above reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 18, 22, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergstrom (US 5,436,161) in view of Steckler (US 4,163,092).

Bergstrom discloses a biosensor comprising a metal surface with a surface layer capable of selective bimolecular interaction using activated surfaces for coupling desired ligands (Column 1, lines 15-22). The metal surface is free electron metal such as copper, silver or aluminum, and a mono layer of a organic molecular, XRY, is applied to the metal surface wherein X binds to the metal and Y serves for coupling with the functional ligands. However, Y may be present in a biocompatible porous matrix such as a hydrogel wherein the matrix is utilized for binding the ligands (Column 4, lines 20-46). Y may be any number of groups used for immobilization in liquid chromatography techniques such as hydroxyl, carboxyl, amino, aldehyde, hydrazide, carbonyl, epoxy or vinyl group (Column 5, lines 1-5). A mixture of different organic molecules XRY may also be used (Column 5, lines 10-15). The matrix, i.e., the hydrogel, has a thickness of 5 to 10,000 angstroms (equivalent to 1 micrometer) (Column 5, lines 30-41). The hydrogel may be polysaccharide such as dextrin or cellulose, a water swellable organic polymer such as polyacrylic acid or polyacrylamide. The hydrogel can be derivative to contain

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hydroxyl, carboxyl, amino, aldehyde, hydrazide, carbonyl, epoxy or vinyl groups (Column 5, lines 61-68). The hydrogel may be generated in situ from a suitable solution of monomers and subsequent crosslinking (Column 6, lines 14-20). Bergstrom also teaches that it is known to coat the metal film with silica and optionally treat it with a silanizing agent (Column 2, lines 9-15).

Bergstrom does not teach that their hydrogel is a cationic hydrogel having ammonium functional groups and is made using the monomers recited in claims 22 and 77.

However, Steckler discloses cationic hydrogels having good water permeability and mechanical properties (Column 1, lines 9-15) and comprising monomers having a quaternized ammonium groups (Column 4; see component (b) and Column 5; Formulae 5). Examples of monomers that may be used include dimethylaminoethyl methacrylate and propyltrimethylammonium chlorides (Column 5, lines 57-58 and Column 6, lines 63-65).

Accordingly, it would have been obvious to one having ordinary skill in the art to substitute the hydrogel used by Bergstrom with the hydrogel taught by Steckler given that Steckler specifically teaches that their cationic hydrogel has good water permeability and mechanical properties.

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Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheeba Ahmed whose telephone number is (703)305-0594. The examiner can normally be reached on Mon-Fri 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Thibodeau can be reached on (703)308-2367. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-5408 for regular communications and (703)305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)306-5665.



Sheeba Ahmed

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January 27, 2003